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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,579	08/25/1999	MICHAEL MEYRICK BURRELL	9341-018-999	6768

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02/24/2004

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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34-

Office Action Summary

Application No.

09/383,579

Applicant(s)

BURRELL ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-36 is/are pending in the application.
- 4a) Of the above claim(s) 24-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-23 and 34-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/4/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 19-36 are pending.
2. Applicant's election with traverse of Group I, claims 19-23, 31 and 34-36 including SEQ ID NO:9, the cucumber expansin nucleic acid sequence, filed 11/26/2003 is acknowledged. The traversal is on the ground(s) that Applicants contend that the groups designated by the Examiner fail to define compositions and methods, with properties so distinct as to warrant separate Examination and Search. Applicants contend that the claims of Group II directed to nucleic acid sequences in antisense orientation are related to the claims of Group I (sentence bridging pages 10 and 11 of response). Applicants contend that "The search for any of the methods separately classified by the Examiner as the invention of Group II would require an additional search of the **identical** classes wherein the claims of Group I are classified," (page 11, top paragraph). Applicants assert that the methods of Groups I and II are directed to transforming trees with chimeric genes to modify fibre characteristics and are therefore directed to the same invention in all aspects. Applicants contend the orientation of the nucleic acid sequence does not alter the directive of the invention. Applicants contend that the nucleic acid sequences encoding expansin are related to each other both structurally and functionally (page 12, 2nd paragraph).
3. This is not found persuasive because while the search of the prior art for one group may overlap with that of another, they are not co-extensive of each other and thus would be a burden on the Office. In addition, it is recognized in the art, that nucleic acid molecules in antisense orientation are used to down-regulate the expression or reduce the activity of a specific protein whereas over-expressing a nucleic acid molecule in sense orientation is used to upregulate or increase the activity of a specific protein. The class and subclass, as noted in the restriction, are

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only given as an example. In the instant application, Group II could also have been classified in class 800, subclass 285. Each Group requires a separate search because the mechanisms by which they operate and the starting material and method steps are all distinct. Lastly, nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. A search of one sequence for prior art does not adequately search any other sequence that exhibits less than 100% sequence identity to said sequence.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24-33 have been withdrawn from consideration because the claims are drawn to non-elected inventions. Claim 31 is drawn to a chimaeric gene as recited in claims 25-30, which are drawn to SEQ ID NOs:1-6.

4. Claims 19-23, and 34-36 are examined in the present office action.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on 8/29/1998. It is noted, however, that applicant has not filed a certified copy of the United Kingdom application as required by 35 U.S.C. 119(b).

Specification

6. Claims 34 and 36 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on a claim that is multiple dependent. See MPEP § 608.01(n).

Information Disclosure Statement

7. Four publications listed on form 1449 have not been considered as they were not provided by the Applicant. As stated in the MPEP § 1.98 (a) Any information disclosure statement filed under § 1.97 shall include: A legible copy of each publication or that portion which caused it to be listed.

Claim Objections

8. Claims 19, 20, 22, 34, and 36 are objected to for reading on non-elected inventions. Correction is required.

Claim 19, line 1, is objected to for reciting "in trees". This recitation is redundant.

Claims 20-23, and 35, line 1, are objected to for reciting the article "A" instead of --The--.

Claims 22 and 23, line 2, are objected to for reciting "in a normal reading frame direction". For the sake of clarity, the Examiner suggests replacing "in a normal reading frame direction" with --in sense orientation-- (See page 12, 3rd paragraph for support).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 19-23, and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

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In claim 19, line 7, the metes and bounds of “substantially similar” have not been defined. “Substantially” is a relative term and hence it is not known what level of similarity is encompassed.

In claim 19, line 7, the metes and bounds of “having the same function” have not been defined. Applicants have not explicitly defined the “function” of the isolated nucleic acids. Applicants put forth a number of hypotheses as to the mechanism or “function” of expansins, but an explicit definition or one that is specific to expansins is not provided (page 7, 1st paragraph).

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 19-23 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of transforming trees to modify fiber characteristics comprising transforming a plant with a chimaeric gene comprising a promoter operably linked to a “part thereof” a nucleic acid sequence of SEQ ID NO:9 encoding a cucumber expansin, or sequences substantially similar to said nucleic acid sequence and having the same function, or combinations thereof.

Applicants disclose the cucumber expansin of SEQ ID NO:9.

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Applicants do not identify essential regions of the cucumber expansin protein encoded by SEQ ID NO:9, nor do Applicants describe any polynucleotide sequences that are a “part thereof” of SEQ ID NO:9 or are “substantially similar thereto and having the same function” as the protein encoded by SEQ ID NO:9 or “combinations thereof”. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicants fail to describe a representative number of polynucleotide sequences encoding an expansin protein falling within the scope of the claimed genus of polynucleotides that are included in “a part thereof” or are “substantially similar thereto and having the same function, or combinations thereof”. Applicants only describe a single cDNA sequence of SEQ ID NO:9. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential

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for the expansin protein, it remains unclear what features identify a cucumber expansin protein. Since the genus of expansin proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Scope of Enablement

11. Claims 19-23 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims drawn to a method of decreasing plant height and/or internode length comprising transforming *Eucalyptus* with SEQ ID NO:9 operably linked in sense orientation to the 35S promoter (page 21-22), does not reasonably provide enablement for claims broadly drawn to a method of transforming trees to modify fiber characteristics comprising transforming a plant with a nucleic acid sequence comprising SEQ ID NO:9, parts thereof, sequences substantially similar thereto and having the same function, or combinations thereof, or wherein the nucleic acid sequence is an mRNA, or a tree transformed therewith, or a seed of a tree transformed therewith. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior

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art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method of transforming trees to modify fiber characteristics comprising transforming a plant with a chimaeric gene comprising a promoter operably linked to a nucleic acid sequence encoding an expansin, said nucleic acid sequence set forth in SEQ ID NO:9, a part thereof, sequences substantially similar to said nucleic acid sequence and having the same function, or combinations thereof, wherein said nucleic acid sequence is an mRNA, wherein said nucleic acid or part thereof is arranged in normal reading frame direction and said method decreases the internode length and or plant height, a tree transformed therewith, or a seed of a tree transformed therewith.

The specification provides guidance for *Eucalyptus* transformation with SEQ ID NO:9 operably linked to the 35S promoter to cause a reduction in the overall height of the plant and concomitant reduction in internode length (paragraph bridging pages 21 and 22 and Table 3).

The specification fails to provide guidance for methods to modify fiber characteristics in trees comprising SEQ ID NO:9, parts of SEQ ID NO:9, or sequences substantially similar to SEQ ID NO:9 or combinations therewith, or comprising an mRNA sequence.

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids of a sequence that is “a part thereof” or a sequence that is “substantially similar” will encode a protein with the same activity as a protein encoded by SEQ ID NO:9. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein’s sequence where amino acid substitutions can be made with a reasonable expectation of

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maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

The state-of-the-art teaches that overexpressing expansins in plants lead to unpredictable developmental results. Choi et al (2003, The Plant Cell 15 :1386-1398) teach constitutive overexpression of a rice expansin gene, OsEXP4, in rice caused 12% of the overexpressors to grow taller and 88% of the overexpressors to grow that shorter than the control. In addition, most overexpressors developed at least two additional leaves (abstract). Lee et al (2003, Plant Physiology 131:985-997) teach overexpressing a soybean expansin gene in tobacco seedlings, caused the roots to exhibit accelerated root growth, and the roots showed insensitivity to obstacle-touching stress (abstract).

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:9 as probes or by designing primers to undisclosed regions of SEQ ID NO:9 and isolating or amplifying fragments, or sequences substantially similar to SEQ ID NO:9, subcloning the fragments or sequences substantially similar to SEQ ID NO:9, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce plants with modified fiber

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characteristics and are considered to be a part of SEQ ID NO:9 or are considered substantially similar to SEQ ID NO:9.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the broadly claimed invention, and therefore the broadly claimed invention is not enabled.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 19, 21-22, 34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by John et al (January, 1997, U.S. Patent Number 5,597,718).

The claims are drawn to a method of transforming trees to modify fiber characteristics comprising incorporating into the plant genome a chimaeric gene comprising a promoter and a part of a nucleic acid sequence or a sequence substantially similar to a sequence encoding an expansin, said sequence having the same function, or wherein said nucleic acid is a cDNA or genomic DNA, or wherein said nucleic acid is in sense orientation, and a tree transformed with said nucleic acid, and seeds from said tree.

John et al teach a cDNA nucleic acid sequence that is “a part of” a nucleic acid encoding an expansin operably linked in sense orientation to a promoter and transformed into a cotton plant to produce a cotton plant with fibers having modified characteristics (columns 15-26). It would be an inherent property of the method taught by John et al to generate seed from the transgenic plants. Given that an explicit definition of the function of expansin is not provided,

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no weight is given to this limitation. "A part of" is interpreted to read on one base pair. The Office interprets the meaning of "tree" as defined by the Merriam and Webster dictionary (Merriam-Webster OnLine, 2004, WWW.M-W.com) to be: **a)** a woody perennial plant having a single usually elongate main stem generally with few or no branches on its lower part or **b)** a shrub or herb of arborescent form <rose *trees*> <a banana *tree*>. Given this definition, a cotton plant is considered to be a tree, because it can be grown in arborescent form, and as such, John et al anticipate the claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claim 36 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 36 is drawn to "a seed" of a transformed tree. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny (seeds), it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v.*

Chakrabarty, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy, Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The

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amendment of the claims to recite that the seed comprises the construct that was introduced into the parent would overcome the rejection.

14. Claims 20, 23 and 35 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method of transforming trees to modify fiber characteristics comprising incorporating into the plant genome a chimaeric gene comprising a promoter and nucleic acid sequence of SEQ ID NO:9 derived from cucumber encoding an expansin or parts thereof, sequences substantially similar thereto, wherein the nucleic acid sequence is in sense orientation and the transformed plant has a decrease in internode length and/or plant height and the plant is a eucalypt, aspen, pine or larch.

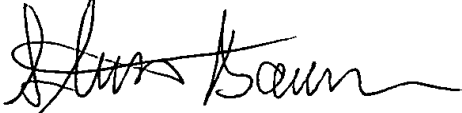
15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read "Stuart F. Baum". The signature is fluid and cursive, with the first name "Stuart" and last name "Baum" clearly distinguishable.

Stuart F. Baum Ph.D.

Patent Examiner

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February 18, 2004